

**REMARKS**

The Examiner has rejected Claims 1, 5, and 15-27, allowed Claims 62, 68 and 70, and objected to Claim 75, but indicated that Claim 75 would be allowable if rewritten in independent form. Applicant has amended Claims 1, 16, 24, 25 and 75, cancelled Claims 2-14, 23 and 76 without prejudice. New claims 77-87 have been added. No new matter is introduced. Support is found in Paragraphs 32, 57, 78, 79 and 91 of the Applicant's publication. Reconsideration and allowance are respectfully solicited.

**I. Rejection of claims under 35 U.S.C 102(b)**

The Examiner has rejected claims 1, 15, 18, 21 and 27 under 35 U.S.C 102 (b) as being anticipated by Miesel et al. (US 6,106,477). The Applicant respectfully requests reconsideration and allowance of the claims.

Claim 1 has been amended to expedite the prosecution of this application to now have the implantable device to be implanted between a transplanted tissue and a native tissue within the patient's body, having the first and the second sensing systems now sense oxygenation of the transplanted and the native tissue, and having the processing system now perform a comparison to facilitate the determination of the condition of the transplanted tissue based on the comparing of the oxygenation sensed by the first and the second sensing systems.

The Examiner on page 2 of the office action asserts that "[s]ince it is measuring a property of the tissue surrounding the blood vessel, such tissue

would be the ambient environment, and an ambient pressure would be a property of the surrounding, second, tissue". While the Applicant agrees the surrounding tissue could be the ambient environment, Applicant disagrees that the ambient pressure is a property of the surrounding tissue.

Applicant refers to the passage in column 10, lines 25-49, at which Miesel discusses what is sensed by the second sensor. In the passage, Miesel states that one sensor (item 146) senses blood pressure and the other sensor (item 147) senses the atmospheric or ambient pressure, not the pressure of surrounding tissue. Miesel again makes clear at lines 33-38 of the same passage that the pressure that is sensed is of the "ambient or atmospheric pressure," not the pressure of surrounding tissue:

"In the pressure field, by having an absolute measure of pressure available at a reference sensor protected from the environment of the measuring sensor, a value close to gage pressure can be obtained, as well as the differential represented by the value of the blood pressure signal. Accordingly, with such an embodiment we can cancel the effects of atmospheric pressure fluctuation as would be done in this art. So here, the sensor under plate 146 would sense the blood affected pressure through a window of preferably something that will transmit a regular approximation of the blood pressure in the vessel above it, such as cured medical adhesive, and the ambient or atmospheric pressure will be sensed above the plate 147, which faces an area of stable body tissue or is blocked off from it."

Applicant's claim 1 includes comparing the oxygenation sensed by the first and the second sensing system. It is clear by the above passage that Miesel does not sense the same physiological property of neighboring tissues. Miesel's second sensor 147 senses the atmospheric pressure and the first sensor 146 senses the blood pressure.

The whole body including the blood (i.e., the tissue of interest in Miesel) is affected by the surrounding atmospheric pressure which increases (offsets) all pressures in the body including that of the blood. Miesel is using the second sensor 147 to measure atmospheric pressure (that is transmitted through the body to the location of the second sensor) and use the latter to "cancel the effects of atmospheric pressure fluctuation" on the measurement of the first pressure sensor 146 that is measuring the blood pressure (see lines 39-40, column 10 of Miesel USP 6,106,447).

Accordingly, Miesel is using the second sensor to measure atmospheric pressure and subtract its value (considered as an undesired offset) from the blood pressure measured by the first sensor. This application is different from the Applicant's disclosure that compares the difference in oxygenation between a transplanted tissue and an adjacent native tissue. Transplanted organs may suffer a decrease in oxygenation due to tissue rejection or thrombosis in their surgically connected vessels. On the other hand, non-transplanted tissue may suffer a decrease in oxygenation only if its blood supply is low in oxygen due to, for example, heart or lung problems.

Miesel et al. also in column 4, lines 14-16 refer to US patent 5,564,434. Miesel claims that their side-sensing chronically implantable absolute pressure sensor is similar or identical to the sensor used in '434 patent. Later in column 6, lines 9-11, Miesel states that the diaphragm surface 1 (Fig. 3) is functionally equivalent or similar to the diaphragm 54 of the '434 Patent. This patent also

discusses the functionality of the sensors and atmospheric pressure compensation.

Therefore, Miesel et al. fails to anticipate the limitations of claim 1. Miesel et al. does not sense oxygenation, is not configured to be transplanted between native and transplanted tissue, is not configured to compare the same property of two tissues, and is not configured to provide information that facilitates determining the condition of a transplanted tissue..

Claims 15, 18, 21 and 27 depend from unanticipated claim1 and are therefore themselves not anticipated.

## **II. Rejection of claims under 35 U.S.C 103(a)**

The Examiner has rejected claims 5, 16, 17 and 26 as being obvious under 35 USC 103(a) over Miesel et al. in view of Sun et al. (US 6,122,536).

Claim 5 has been cancelled and its limitations have been incorporated into independent claim 1.

Sun et al. disclose an implantable sensor and system capable of measuring, controlling and monitoring blood constituents as in Miesel et al. Sun et al. fails to teach the comparing of the oxygenation sensed by a first and a second sensing systems of a transplanted and a native tissue.

There was also no reason for the skilled artisan to have substituted the oxygenation sensors of Sun et al. for the pressure sensors of Miesel et al. It would have made no sense to have measured the oxygenation of the blood vessel in Miesel et al. or to have subtracted the ambient oxygenation from this

measurement. Moreover, such a combination still would not have resulted in a device configured to be transplanted between native and transplanted tissue, a device configured to compare the same property of two tissues, or a device configured to provide information that facilitates determining the condition of a transplanted tissue, all as now required by Claim 1.

Therefore, Sun et al. fails to remedy the deficiencies of Miesel et al. and hence claims 16, 17 and 26 are allowable for the same reasons as claim 1.

### **III. Allowable Subject Matter**

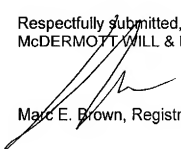
The Examiner previously allowed claims 62, 68 and 70 and indicated that claim 75 would be allowable if rewritten in an independent form. Claim 75 has been amended to be in independent form and is should therefore now be allowable.

### **IV. Conclusion**

The Applicant respectfully requests that the Examiner withdraw the finality of the last office action, and submits that the above amendment and remarks place this application in condition for allowance, which the Applicant respectfully solicits.

Please charge any shortage in fees due in connection with the filing of this paper to Deposit Account 501946 and please credit any excess fees to such deposit account and reference attorney docket no. 64693-094.

Respectfully submitted,  
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